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| EXAMINER | |
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| ART UNIT | PAPER NUMBER |
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* DOMINIK MEYER

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Appeal 2010-002385
Application 10/521,599
Technology Center 1600

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Before DEMETRA J. MILLS, FRANCISCO C. PRATS and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to treating post-operative joint pain. The Examiner rejected the claims for indefiniteness, obviousness, and obviousness-type double patenting.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm the indefiniteness and obviousness-type double patenting rejections, as Appellant did not present substantive arguments traversing those rejections. However, we reverse the Examiner's obviousness rejections.

STATEMENT OF THE CASE

Claims 1, 3-9, 11-17, 26, 28-37, 39-42, and 44-46 stand rejected and are on appeal (App. Br. 4).[2] Claim 1 is representative and reads as follows:

> Claim 1: A method for treating post-operative joint pain, the method comprising:
>
> providing an agent for treating joint pain comprising a neurotoxic substance dissolved in a bio-compatible solvent, wherein said neurotoxic substance is an amide local anesthetic, and wherein said amide local anesthetic is present in said agent for treating joint pain in a concentration whereby said agent for treating joint pain is predominantly toxic to nociceptive nerve fibers but not systemically toxic when injected into a post-operative joint space; and
>
> injecting the agent for treating joint pain into said post-operative joint space as a one time application in an amount sufficient to entail neurolysis.

The Examiner cites the following documents as evidence of unpatentability:

| | | |
|---|---|---|
| Macek | US 3,368,937 | Feb. 13, 1968 |
| Davis | US 3,917,830 | Nov. 4, 1975 |
| Herschler | US 4,296,104 | Oct. 20, 1981 |
| Arias-Alvarez | US 4,657,764 | Apr. 14, 1987 |
| Mueller | US 5,002,761 | Mar. 26, 1991 |
| Oakes | US 5,061,485 | Oct. 29, 1991 |

[2] Appeal Brief filed November 20, 2008.

| | | |
|---|---|---|
| Klaveness | US 5,242,683 | Sep. 7, 1993 |
| Chasin | US 5,942,241 | Aug 24, 1999 |
| Bawa | US 6,261,547 B1 | Jul. 17, 2001 |
| Goldenheim | US 6,248,345 B1 | Jun. 19, 2001 |

K.A. Milligan et al., *Intra-articular bupivacaine for pain relief after arthroscopic surgery of the knee joint in daycase patients*, 43 ANAESTHESIA 563-64 (1988).

Gary R. Strichartz, *Editorial: Every Problem Is an Opportunity, or One Person's Poison Is Another Person's Remedy*, 23 REGIONAL ANESTHESIA AND PAIN MEDICINE 3-6 (1998).

The following rejections are before us for review:

(1) Claim 44, rejected under 35 U.S.C. § 112, second paragraph, as indefinite (Ans. 4);

(2) Claims 1, 3-9, 11-17, 26, 40-42, 44, and 45, rejected under 35 U.S.C. § 103(a) as obvious over Milligan, Bawa, Goldenheim, Arias-Alvarez, and Strichartz (Ans. 4-10);

(3) Claims 1, 3-8, 11, 13, 26, 28, 35, and 40-42, rejected under 35 U.S.C. § 103(a) as obvious over Macek (Ans. 10-13);

(4) Claims 1, 5, 28-37, 39, and 46, rejected under 35 U.S.C. § 103(a) as obvious over Macek, Goldenheim, Strichartz, Davis, Herschler, Oakes, Mueller, Chasin, and Klaveness (Ans. 13-16);

(5) Claims 1, 2, and 40-42, provisionally rejected for obviousness-type double patenting over claims 50 and 51 of copending Application No. 11/722,779 (Ans. 17);

(6) Claims 1, 2, and 40-42, provisionally rejected for obviousness-type double patenting over claims 39-42 of copending Application No. 11/722,857 (Ans. 18);

(7) Claims 1, 2 and 40-42, provisionally rejected for obviousness-type double patenting as being over claims 94-96 of copending Application No. 11/722,484 (Ans. 18-19).

OBVIOUSNESS --

MILLIGAN, BAWA, GOLDENHEIM, ARIAS-ALVAREZ, AND STRICHARTZ

*ISSUE*

The Examiner cites Milligan as administering bupivacaine into patients' knees after arthroscopic surgery (Ans. 5). The Examiner finds, however, that Milligan differs from the claims in that Milligan does not administer the anesthetic at a concentration sufficient to produce neurolysis (*id.* at 6-7).

To remedy that shortcoming, the Examiner cites Strichartz as teaching that higher dosages of the amide anesthetic lidocaine produce neurolysis, and further notes Milligan's disclosure that the amount of anesthetic used in its study did not provide analgesia, thus suggesting an increase in dosage (*id.* at 7-9). To meet features recited in dependent claims, the Examiner cites Bawa (equivalence of levobupivacaine and bupivacaine), Goldenheim (intra-articular administration of amide anesthetics, equivalence of anesthetics such as bupivacaine and lidocaine, addition of secondary active agents), and Arias-Alvarez (inclusion of sodium bisulfite in injected composition) (*id.* at 6).

Appellant contends that the combination of references cited by the Examiner would not have rendered the claims obvious to an ordinary artisan because Milligan's rationale for not increasing the anesthetic dosage was that increased anesthetic concentrations would result in undesirably high systemic concentrations, and because the lack of an anesthetic effect from

intra-articular injections suggested that the pain was outside the knee capsule (App. Br. 10). Moreover, Appellant argues, Strichartz would not have prompted an ordinary artisan to perform a one-time administration of the claimed concentration of therapeutic agent because Strichartz describes a study, performed by Choi,[3] in which patients with chronic pain received a 5% lidocaine solution, but in which none of the patients received an intra-articular injection, and in which the pain returned in all patients (*id.* at 11).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether the evidence of record supports the Examiner's position that an ordinary artisan would have been prompted to treat post-operative joint pain by intra-articularly administering neurolytic concentrations of an amide anesthetic.

*FINDINGS OF FACT ("FF")*

1. The Specification discloses "injecting a neurotoxic, neurolytic and neuroparalytic or long-term analgesic substance (hereafter, and in particular in the claims, termed generically as a 'neurotoxic' substance) into a painful or ailing joint of the human or animal body" (Spec. 3).

2. The Specification discloses that "it was surprisingly found that solutions of high concentrations may act selectively neurolytically upon being inserted into the joint cavity (neurotoxic effect)" (*id.*).

3. The Specification discloses that highly concentrated local anesthetics "were found particularly effective, for instance: Lidocaine, preferably at a concentration of more than 6 %, the maximum dose being 500 mg; . . .

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[3] Young K. Choi et al., *The Use of 5% Lidocaine for Prolonged Analgesia in Chronic Pain Patients: A New Technique*, 23 REGIONAL ANESTHESIA AND PAIN MEDICINE 96-100 (1998).

mepivacaine, preferably at a concentration of more than 5 %, the maximum dose being 500 mg; [and] bupivacaine, preferably at a concentration of more than 1.5 %, the maximum dose being 150 mg" (*id.* at 5).

4. Milligan describes a randomized double-blind study that compared the "influence on postoperative pain of equal volumes of one of two concentrations of bupivacaine (0.25%. 0.5%), or saline 0.9%, injected into the knee joint after arthroscopy. The results showed that intra-articular bupivacaine had no significant analgesic effect in either concentration" (Milligan 563 (abstract)).

5. Milligan describes its findings and conclusions as follows:

> This study shows that direct injection of bupivacaine 50 mg or 100 mg into the knee joint after arthroscopy provides little analgesia. The plasma levels were all below reported toxic plasma bupivacaine concentrations in man (2-4 μg/ml). This might support a case for use of a higher concentration of bupivacaine, but the authors do not propose to undertake such a study. Small molecules are known to traverse the synovium rapidly to reach the joint capsule, which is perforated by articular vessels and nerve endings. Plasma bupivacaine concentrations in the present study confirm this. The lack of analgesia may suggest that the source of pain after arthroscopy is outside the capsule of the knee joint.

(*Id.* at 564 (citations omitted).)

6. In an editorial, Strichartz discloses that a case report by Choi and Liu, in the same issue of the same journal, "is futuristic, intriguing, and exciting. Choi and Liu have 'taken lemons and turned them into lemonade.' Through innovative thought, they introduce the possibility that a common spinal anesthetic used differently might double as a neurolytic agent in the treatment of neuropathic pain" (Strichartz 3).

7. Strichartz notes that while 5% lidocaine, or spinal lidocaine, was known to have serious side effects, and to be irreversibly toxic to nerves, Choi and Liu nonetheless reasoned that this neurotoxicity would be useful in treating three patients suffering from chronic painful conditions (*id.*).

8. Specifically, Choi discloses a study in which "5% lidocaine with 7.5% dextrose was injected into three patients with trigeminal neuralgia, post-herpetic occipital neuralgia, and intercostal neuralgia, respectively. The patients were followed for one and a half years" (Choi 96 (abstract)).

9. Choi discloses that one patient received a "trigeminal block and one patient received an occipital nerve block. Both patients reported immediate and complete pain relief lasting 14 and 8 months, respectively. One patient, given an intercostal nerve block, received immediate pain relief lasting 5 weeks. None of these patients exhibited any appreciable side effects or complications" (*id.*).

10. Based on its study, Choi concludes that "5% lidocaine may be used safely and effectively for the purpose of prolonged analgesia in selected patients with intractable chronic pain syndromes" (*id.*).

*PRINCIPLES OF LAW*

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question, but nonetheless reaffirmed that

> it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

*Id.* at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

Ultimately, therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

It is well settled, however, that "the discovery of an optimum value of a variable in a known process is usually obvious." *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1368 (Fed. Cir. 2007). Thus, "a *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties." *In re Peterson,* 315 F.3d 1325, 1329 (Fed. Cir. 2003).

*ANALYSIS*

We agree with Appellant that the evidence of record does not support the Examiner's position that an ordinary artisan would have been prompted to treat post-operative joint pain by intra-articularly administering neurolytic concentrations of an amide anesthetic.

Independent claims 1 and 40 both recite methods of treating post-operative joint pain by injecting into the subject's joint a neurotoxic substance at a concentration that "entail[s] neurolysis." The Specification provides that bupivacaine, at a concentration of more than 1.5 %, with a maximum dose of 150 mg, is an example of such a treatment (FF 3). As the Examiner points out, Strichartz discloses that 5% lidocaine also produces a neurolytic effect (FF 6).

We are not persuaded, however, that an ordinary artisan would have been prompted by Strichartz, or Choi's underlying study, to have increased the bupivacaine dosage administered by Milligan to a level encompassed by claims 1 and 40. Nor are we persuaded that Strichartz would have prompted an ordinary artisan to intra-articularly administer neurolytic concentrations of lidocaine, or any other anesthetic, to a subject suffering from post-operative joint pain.

We acknowledge Milligan's disclosure that 0.5% bupivacaine failed to provide analgesia to subjects suffering from post-operative joint pain (FF 4, 5). Despite this, Milligan discloses that higher anesthetic dosages were not investigated because of the potential for excessive plasma concentrations of the drug (FF 5).

Moreover, Strichartz discloses that neurolytic concentrations of lidocaine were known to have potentially serious side effects (FF 7). Thus, while Strichartz may have praised the results obtained by Choi (FF 6), Choi ultimately concluded that neurolytic concentrations of lidocaine "may be used safely and effectively for the purpose of prolonged analgesia *in selected patients with intractable chronic pain syndromes*" (Choi 96 (abstract) (emphasis added) (FF 10)).

Thus, the patient populations at issue are very different between Choi and Milligan. As reported by Strichartz, Choi is focusing on desperate patients in chronic, unrelieved pain (FF 7), while Milligan is treating a patient population undergoing temporary postoperative pain (FF 4).

In the instant case, the Examiner points to no clear evidence of record, in any of the cited references, suggesting that an ordinary artisan would have considered it suitable, or even desirable, to treat Milligan's post-arthroscopy patients with a therapeutic regimen used for treating the intractable chronic pain conditions described by Strichartz and Choi, particularly in view of the potential downsides of increased anesthetic dosages disclosed by Milligan and Strichartz. Moreover, given the art-recognized downsides of excessively high anesthetic dosages, we are not persuaded that the Examiner has adequately explained why Strichartz's disclosure of using neurolytic concentrations of anesthetics to treat intractable chronic pain would have prompted an ordinary artisan to essentially triple the bupivacaine dosage, or provide its equivalent dosage of lidocaine, to treat the pain experienced by Milligan's post-arthroscopic knee surgery patients.

Thus, given the differences between the conditions described by Milligan and Strichartz/Choi, and the downsides to administering high concentrations of bupivacaine and lidocaine taught by Milligan and Strichartz, we are not persuaded that an ordinary artisan would have been prompted to treat post-operative joint pain by intra-articularly administering neurolytic concentrations of the therapeutic agents encompassed by independent claims 1 and 40. Accordingly, we reverse the Examiner's obviousness rejection of those claims, and their dependents, over Milligan, Bawa, Goldenheim, Arias-Alvarez, and Strichartz.

OBVIOUSNESS -- MACEK

*ISSUE*

The Examiner found that Macek met the claims' requirement of administering a neurolytic concentration of the therapeutic agent by disclosing administration of a composition containing 5 to 20 parts of lidocaine or mepivacaine, which would reasonably be interpreted as describing a composition containing 5 to 20 percent of those drugs (Ans. 11 and 22-23 (citing Macek at claims 1, 11, and 12)).

Appellant contends that, when the claims of Macek are viewed in light of the remainder of the patent, in particular the Examples, an ordinary artisan would not reasonably have interpreted Macek as describing administration of a composition having 5 to 20 percent (App. Br. 15-17).

In view of the positions advanced by Appellant and the Examiner, the issue with respect to this rejection is whether the evidence of record supports the Examiner's position that an ordinary artisan would have interpreted Macek as describing administration of a composition containing a neurolytic concentration of lidocaine or mepivacaine.

*FINDINGS OF FACT*

11. Macek discloses "an injectable steroid solution containing a 21-phosphate of an anti-inflammatory steroid such as dexamethasone 21-phosphate and containing also a local anesthetic. The steroid is one which is advantageously administered by intramuscular, intrasynovial, intra-articular and soft tissue injection" (Macek, col. 1, ll. 15-20).

12. Macek discloses that by combining the "21-phosphate steroid and an aromatic amide selected from the group consisting of lidocaine and mepivacaine in specific proportions" the resulting composition is "quickly

operative after injection and . . . is sufficiently stable that it may be stored for extensive periods of time up to two years or more," and also allows the two agents to be "mutually effective throughout a common pH range and . . . not react with one another to form a water-insoluble salt" (*id.* at col. 1, ll. 57-70).

13. Examples 1, 2, 8, 9, and 10 of Macek disclose injectable compositions containing 0.893 weight % of lidocaine (*id.* at cols. 3-5).

14. Examples 3 and 4 of Macek disclose injectable compositions containing 0.45 weight % of lidocaine, Example 5 discloses a composition containing 0.5 weight % mepivacaine, and Example 6 discloses a composition containing 1% by weight mepivacaine (*id.*).

15. Example 7 of Macek is a table illustrating "the relative proportions of dexamethasone and lidocaine base, or dexamethasone and mepivacaine, which vary from 1-20 parts by weight of dexamethasone to 5-20 parts by weight of lidocaine base, or, in the case of mepivacaine, preferably 1-10 mg. per ml. when the dexamethasone 21-phosphate is present in a concentration of 1-10 mg./ml." (*id.* at col. 4, ll. 56-62).

16. Claim 1 of Macek recites "[a] clear, injectable solution consisting essentially of water, about 5-20 parts by weight of a compound selected from the group consisting of lidocaine and mepivacaine and about 1-20 parts by weight of a [21-phosphate steroid] compound . . . ." (*id.* at col. 6, ll. 22-44)

17. Claim 11 of Macek, an independent claim, recites "[a] clear, injectable solution consisting essentially of the following ingredients in the quantities stated," the ingredients including 8.93 milligrams of lidocaine

base per milliliter of solution (*id.* at col. 7, l. 20, through col. 8, l. 6), which equates to about 0.893 weight % of lidocaine in the composition.

18. Claim 12 of Macek, an independent claim, recites "[a] clear, injectable solution consisting essentially of the following ingredients in the quantities state[d]," which include 5 milligrams of mepivacaine per milliliter of solution (*id.* at col. 8, ll. 7-16), which equates to 0.5% by weight of mepivacaine in the composition.

*ANALYSIS*

We agree with Appellant that the evidence of record does not support the Examiner's position that an ordinary artisan would have interpreted Macek as describing administration of a composition containing a neurolytic concentration of lidocaine or mepivacaine.

As noted above, independent claims 1 and 40 both recite methods of treating post-operative joint pain by injecting into the subject's joint a neurotoxic substance at a concentration that "entail[s] neurolysis." As also noted above, the Specification provides that lidocaine, at a concentration of more than 6 %, with a maximum dose of 500 mg, and mepivacaine, at a concentration of more than 5 %, are examples of such a treatment (FF 3).

In contrast, the highest percentage of either of these two ingredients in any composition specifically disclosed by Macek is one percent (*see* FF 13-15, 17, and 18), which is several-fold lower than the concentration disclosed in the Specification as providing the neurolytic effect required by claims 1 and 40.

We acknowledge that a reference's disclosure is not limited to its examples. In the instant case, however, the Examiner has not adequately explained why an ordinary artisan would have increased the concentration of

the anesthetics in Macek's compositions the five- to six-fold needed to achieve the neurolytic effect required in the claims.

Nor are we persuaded that the recitation in Macek's claim 1 of "5-20 parts by weight of a compound selected from the group consisting of lidocaine and mepivacaine" (FF 16) amounts to a positive disclosure of five to twenty weight percent of those ingredients in the claimed composition. The Examiner does not point to any specific teaching in Macek suggesting that "parts" equates to concentration percentages, or that such high concentrations of the anesthetics should be used in its compositions. Rather, the only specific teachings regarding absolute concentrations of the anesthetics appear in Examples 1-6 and 8-10, which, as discussed above disclose 1% anesthetic at most.

Thus, in our view, an ordinary artisan would have interpreted the "5-20 parts by weight" of lidocaine/mepivacaine in Macek's claim 1 as reciting only the relative proportion of the anesthetic to the 21-phosphate steroid compound, as described in Macek's Example 7 (FF 15). Accordingly, as we are not persuaded that the Examiner has adequately explained how or why Macek teaches or suggests administering the amount of therapeutic agent recited in independent claims 1 and 40, we reverse the Examiner's obviousness rejection of those claims, and their dependents, over Macek.

The Examiner also rejected claims 1, 5, 28-37, 39, and 46 as obvious over Macek, Goldenheim, Strichartz, Davis, Herschler, Oakes, Mueller, Chasin, and Klaveness (Ans. 13-16). As discussed above, we are not persuaded that Strichartz would have prompted an ordinary artisan to administer compositions containing neurolytic concentrations of anesthetics to patients experiencing post-operative joint pain. As the Examiner points to

no teaching in any of the other cited references that remedies this shortcoming in Macek and Strichartz, we also reverse the Examiner's obviousness rejection of claims 1, 5, 28-37, 39, and 46 over Macek, Goldenheim, Strichartz, Davis, Herschler, Oakes, Mueller, Chasin, and Klaveness.

INDEFINITENESS

The Examiner rejected claim 44 as indefinite under 35 U.S.C § 112, second paragraph, because the recitation "the mixture" in line 2 of the claim lacked sufficient antecedent basis (Ans. 4).

Appellant responded only that he "attempted to amend claim 44 in an Amendment After Final to address this error, but the Amendment After Final was not entered. Applicant reserves the right to file an amendment to amend claim 44 subsequent to a Decision on this appeal" (App. Br. 19).

In view of the absence of substantive argument from Appellant, we summarily affirm this rejection.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The Examiner provisionally rejected claims 1, 2, and 40-42 for obviousness-type double patenting over claims 50 and 51 of copending application No. 11/722,779, claims 39-42 of copending application No. 11/722,857, and claims 94-96 of copending application No. 11/722,484 (Ans. 17-19).

Appellant responded by stating only that he "reserves the right to file terminal disclaimers to obviate the double-patenting rejections subsequent to a Decision on this appeal" (App. Br. 19).

In view of the absence of substantive argument from Appellant, we summarily affirm these rejections.

## SUMMARY

We affirm the Examiner's rejection of claim 44 under 35 U.S.C. § 112, second paragraph, as indefinite.

We reverse the Examiner's rejection of claims 1, 3-9, 11-17, 26, 40-42, 44, and 45 under 35 U.S.C. § 103(a) as obvious over Milligan, Bawa, Goldenheim, Arias-Alvarez, and Strichartz.

We also reverse the Examiner's rejection of claims 1, 3-8, 11, 13, 26, 28, 35, and 40-42 as obvious over Macek.

We also reverse the Examiner's rejection of claims 1, 5, 28-37, 39, and 46 as obvious over Macek, Goldenheim, Strichartz, Davis, Herschler, Oakes, Mueller, Chasin, and Klaveness.

We affirm the Examiner's provisional rejections of claims 1, 2, and 40-42 for obviousness-type double patenting over claims 50 and 51 of copending application No. 11/722,779, claims 39-42 of copending application No. 11/722,857, and claims 94-96 of copending application No. 11/722,484.

## TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

## AFFIRMED-IN-PART

alw

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